



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2016-0725; FRL-9403-01-OCSPP]

Colour Index Pigment Violet 29 (PV29); Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of and requesting public comment on a draft revision to the risk determination for the Colour Index Pigment Violet 29 (PV 29) risk evaluation issued under TSCA. The draft revision to the PV 29 risk determination was developed following a review of the first ten risk evaluations issued under TSCA that was done in accordance with Executive Orders and other Administration priorities, including those on environmental justice, scientific integrity, and regulatory review, and this draft revision reflects the announced policy changes to ensure the public is protected from unreasonable risks from chemicals in a way that is supported by science and the law.

Specifically, in this draft revision to the risk determination EPA finds that PV 29, as a whole chemical substance, presents an unreasonable risk of injury to health when evaluated under its conditions of use. This draft revision would supersede the condition of use-specific no unreasonable risk determinations in the January 2021 PV 29 risk evaluation (and withdraw the associated order) and make a revised determination of unreasonable risk for PV 29 as a whole chemical substance. In addition, this draft revised risk determination does not reflect an assumption that workers always appropriately wear personal protective equipment (PPE).

DATES: Comments must be received on or before [INSERT DATE 45 DAYS AFTER PUBLICATION IN THE *Federal Register*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-EPA-HQ-OPPT-2016-0725, using the Federal eRulemaking Portal at

<https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is by appointment only. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Todd Coleman, Office of Pollution Prevention and Toxics (7404T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-1208; email address: Coleman.Todd@EPA.gov

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

This action is directed to the public in general. This action may, however, be of interest to those involved in the manufacture, processing, distribution, use, disposal, and/or the assessment of risks involving chemical substances and mixtures. You may be potentially affected by this action if you manufacture (defined under TSCA to include import), process (including recycling), distribute in commerce, use or dispose of PV 29, including PV 29 in products. Since other entities may also be interested in this draft revision to the risk determination, the EPA has not attempted to describe all the specific entities that may be affected by this action.

B. What is EPA's authority for taking this action?

TSCA section 6, 15 U.S.C. 2605, requires EPA to conduct risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the

environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use. 15 U.S.C. 2605(b)(4)(A). TSCA sections 6(b)(4)(A) through (H) enumerate the deadlines and minimum requirements applicable to this process, including provisions that provide instruction on chemical substances that must undergo evaluation, the minimum components of a TSCA risk evaluation, and the timelines for public comment and completion of the risk evaluation. TSCA also requires that EPA operate in a manner that is consistent with the best available science, make decisions based on the weight of the scientific evidence, and consider reasonably available information. 15 U.S.C. 2625(h), (i), and (k).

The statute identifies the minimum components for all chemical substance risk evaluations. For each risk evaluation, EPA must publish a document that outlines the scope of the risk evaluation to be conducted, which includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that EPA expects to consider. 15 U.S.C. 2605(b)(4)(D). The statute further provides that each risk evaluation must also: (1) integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on relevant potentially exposed or susceptible subpopulations; (2) describe whether aggregate or sentinel exposures were considered and the basis for that consideration; (3) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use; and (4) describe the weight of the scientific evidence for the identified hazards and exposures. 15 U.S.C. 2605(b)(4)(F)(i) through (ii) and (iv) through (v). Each risk evaluation must not consider costs or other non-risk factors. 15 U.S.C. 2605(b)(4)(F)(iii).

EPA has inherent authority to reconsider previous decisions and to revise, replace, or repeal a decision to the extent permitted by law and supported by reasoned explanation. *FCC v.*

Fox Television Stations, Inc., 556 U.S. 502, 515 (2009); *see also Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 42 (1983).

C. What action is EPA taking?

EPA is announcing the availability of and seeking public comment on a draft revision to the risk determination for the risk evaluation for PV 29 under TSCA, published in January 2021 (Ref. 1). EPA is specifically seeking public comment on the draft revision to the risk determination for the risk evaluation where the agency intends to determine that PV 29, as a whole chemical, presents an unreasonable risk of injury to health when evaluated under its conditions of use. This whole chemical approach to determining unreasonable risk to health is permissible under EPA's statutory obligations under TSCA section 6(b)(4) and the implementing regulations and would revise and replace section 5 of the risk evaluation for PV 29 where the findings of unreasonable risk to health were previously made for the individual conditions of use evaluated.

This revision would be consistent with EPA's plans to revise specific aspects of the first ten TSCA chemical risk evaluations in order to ensure that the risk evaluations better align with TSCA's objective of protecting health and the environment. Under the draft revision, the same ten conditions of use would continue to drive the unreasonable risk determination for PV 29. Removing the assumptions of PPE use in making the whole chemical risk determination for PV 29 would not alter the conditions of use or worker subpopulations that drive the unreasonable risk determination for PV 29. Overall, ten conditions of use drive the PV 29 whole chemical unreasonable risk determination due to risks identified for human health. The full list of the conditions of use evaluated for the PV 29 risk evaluation is in Table 5-1 of the risk evaluation (Ref. 1).

D. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through [regulations.gov](https://www.regulations.gov) or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI

information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. Tips for preparing your comments. When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

II. Background

A. Why is EPA re-issuing the risk determination for the PV 29 risk evaluation conducted under TSCA?

In 2016, as directed by TSCA section 6(b)(2)(A), EPA chose the first ten chemical substances to undergo risk evaluations under the amended TSCA. These chemical substances are asbestos, 1-bromopropane, carbon tetrachloride, C.I. Pigment Violet 29 (PV 29), cyclic aliphatic bromide cluster (HBCD), 1,4-dioxane, methylene chloride, n-methylpyrrolidone (NMP), perchloroethylene (PCE), and trichloroethylene (TCE).

From June 2020 to January 2021, EPA published risk evaluations on the first ten chemical substances, including for PV 29 in January 2021. The risk evaluations included individual unreasonable risk determinations for each condition of use evaluated. The determinations that particular conditions of use did not present an unreasonable risk were issued by order under TSCA section 6(i)(1).

In accordance with Executive Order 13990 (Ref. 2) and other Administration priorities (Refs. 3, 4, and 5), EPA is reviewing the risk evaluations for the first ten chemical substances to ensure that they meet the requirements of TSCA, including conducting decision making in a manner that is consistent with the best available science.

As a result of this review, EPA announced plans to revise specific aspects of the first ten

risk evaluations in order to ensure that the risk evaluations appropriately identify unreasonable risks and thereby help ensure the protection of human health and the environment available here <https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations>. To that end, EPA is reconsidering two key aspects of the risk determinations for PV 29 published in January 2021. First, based on EPA's review, EPA proposes that the appropriate approach to these determinations under the statute and implementing regulations is to make an unreasonable risk determination for PV 29 as a whole chemical substance, rather than making unreasonable risk determinations separately on each individual condition of use evaluated in the risk evaluation. Second, EPA proposes that the risk determination should be explicit that it does not rely on assumptions regarding the use of personal protective equipment (PPE) in making the unreasonable risk determination under TSCA section 6; rather, the use of PPE would be considered during risk management.

This action pertains only to the risk determination for PV 29. While EPA intends to consider and may take additional similar actions on other of the first ten chemicals, EPA is taking a chemical-specific approach to reviewing the risk evaluations and is incorporating new policy direction in a surgical manner, while being mindful of the Congressional direction on the need to complete risk evaluations and move toward any associated risk management activities in accordance with statutory deadlines. To the extent the Agency deems appropriate, additional actions may follow that are specific to each of the chemical substances for which EPA has issued final risk evaluations under TSCA section 6.

B. What is a whole chemical view of the unreasonable risk determination for the PV 29 risk evaluation?

TSCA section 6 repeatedly refers to determining whether a chemical *substance* presents unreasonable risk under its conditions of use. Stakeholders have disagreed over whether a chemical substance should receive: a single determination that is comprehensive for the chemical substance after considering the conditions of use, referred to as a whole-chemical determination;

or multiple determinations, each of which is specific to a condition of use, referred to as condition-of-use-specific determinations. EPA acknowledges a lack of specificity in the statute and inconsistency in the regulations with respect to the presentation of risk determinations in TSCA risk evaluations.

The proposed risk evaluation procedural rule was premised on the whole chemical approach to making unreasonable risk determinations (Ref. 6). EPA acknowledged a lack of specificity in whether the statute compelled EPA's risk evaluations to address all conditions of use of a chemical substance or whether EPA had discretion to evaluate some subset of conditions of use (i.e., to scope out some manufacturing, processing, distribution in commerce, use, or disposal activities). The proposed rule, however, was unambiguous on the point that unreasonable risk determinations would be for the chemical substance as a whole, even if based on a subset of uses. (See Ref. 6 at pgs. 7565-66: "TSCA section 6(b)(4)(A) specifies that a risk evaluation must determine whether 'a chemical substance' presents an unreasonable risk of injury to health or the environment 'under the conditions of use.' The evaluation is on the chemical substance—not individual conditions of use—and it must be based on 'the conditions of use.' In this context, EPA believes the word 'the' is best interpreted as calling for evaluation that considers all conditions of use."). In the proposed regulatory text, EPA proposed to "determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use as identified in the final scope document..." (Ref. 6 at pg. 7480).

As stated in the final risk evaluation procedural rule (Ref. 7): "As part of the risk evaluation, EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under each condition of uses [sic] within the scope of the risk evaluation, either in a single decision document or in multiple decision documents." (See also 40 CFR 702.47). For the unreasonable risk determinations in the first ten risk evaluations, EPA applied this provision by making individual risk determinations for each condition of use

evaluated in each risk evaluation (i.e., the condition-of-use-specific approach to risk determinations). That approach was based on one particular passage in the preamble to the final risk evaluation procedural rule: “The final step of a risk evaluation is for EPA to determine whether the chemical substance, under the conditions of use, presents an unreasonable risk of injury to health or the environment. EPA will make individual risk determinations for all uses identified in the scope. This part of the regulation is slightly amended from the proposed rule, to clarify that the risk determination is part of the risk evaluation, as well as to account for the revised approach to that [sic] ensures each condition of use covered by the risk evaluation receives a risk determination.” (Ref. 7 at pg. 33744).

In contrast to this portion of the preamble of the final risk evaluation procedural rule, the regulatory text itself and other statements in the preamble reference a risk determination *for the chemical substance* under its conditions of use, rather than separate risk determinations for each of the conditions of use of a chemical substance. In the key regulatory provision excerpted above from 40 CFR 702.47, the text explains that, “[a]s part of the risk evaluation, EPA will determine whether *the chemical substance* presents an unreasonable risk of injury to health or the environment under each condition of uses [sic] within the scope of the risk evaluation, either in a single decision document or in multiple decision documents” (Ref. 7, emphasis added). Other language reiterates this perspective. For example, 40 CFR 702.31(a) states that the purpose of the rule is to establish the EPA process for conducting a risk evaluation to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment as required under TSCA section 6(b)(4)(B). Likewise, there are recurring references to whether the chemical substance presents an unreasonable risk in 40 CFR 702.41(a). See, for example, 40 CFR 702.41(a)(6), which states: “[t]he extent to which EPA will refine its evaluations for one or more condition of use in any risk evaluation will vary as necessary to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment.” Notwithstanding the one preambular statement about condition-of-use-specific risk

determinations, the preamble to the final rule also contains support for a risk determination on the chemical substance as a whole. In discussing the identification of the conditions of use of a chemical substance, the preamble notes that this task inevitably involves the exercise of discretion on EPA's part, and, "as EPA interprets the statute, the Agency is to exercise that discretion consistent with the objective of conducting a technically sound, manageable evaluation to determine whether a chemical substance—not just individual uses or activities—presents an unreasonable risk." (Ref. 7 at pg. 33729).

Therefore, notwithstanding EPA's choice to issue condition-of-use-specific risk determinations to date, EPA interprets its risk evaluation regulation to also allow the Agency to issue whole-chemical risk determinations. Either approach is permissible under the regulation. A panel of the Ninth Circuit Court of Appeals also recognized the ambiguity of the regulation on this point. *Safer Chemicals v. EPA*, 943 F.3d 397, 413 (9th Cir. 2019) (holding a challenge about "use-by-use risk evaluations [was] not justiciable because it is not clear, due to the ambiguous text of the Risk Evaluation Rule, whether the Agency will actually conduct risk evaluations in the manner Petitioners fear"). EPA plans to consider the appropriate approach for each chemical substance risk evaluation on a case-by-case basis, taking into account considerations relevant to the specific chemical substance in light of the Agency's obligations under TSCA. The Agency expects that this case-by-case approach will provide greater flexibility in the Agency's ability to evaluate and manage unreasonable risk from individual chemical substances. For instance, circumstances in which an unreasonable risk determination is primarily driven by a single condition of use that does not impact or intersect with other evaluated uses (such as for example, a single consumer use of a substance out of a wide range of other manufacturing, processing and consumer uses evaluated) may warrant different treatment than circumstances in which the majority of the chemical substance's conditions of use contribute to unreasonable risk, and the Agency might adopt different approaches to the risk determinations in those particular instances. EPA anticipates that this flexibility will better serve TSCA's objectives by helping ensure that

EPA is best positioned to present, and initiate risk management to address, chemical-specific unreasonable risk determinations. EPA believes this is a reasonable approach under TSCA and the Agency's implementing regulations.

With regard to the specific circumstances of PV 29, as further explained in this notice, EPA proposes that a whole chemical approach better aligns with TSCA's objective of protecting health and the environment. For PV 29, EPA favors the whole chemical approach based in part on the benchmark exceedances for multiple conditions of use (spanning across most aspects of the chemical lifecycle—from manufacturing (including import), processing, commercial and industrial use, and disposal) for health of workers and occupational non-users and the irreversible health effects (specifically alveolar hyperplasia) associated with PV 29 exposures. Since the chemical-specific properties cut across the conditions of use within the scope of the risk evaluation, the Agency's risk findings and conclusions encompass the majority of those conditions of use, and the Agency is better positioned to achieve its TSCA objectives for PV 29 when issuing a whole chemical determination for PV 29, EPA concludes that the Agency's risk determination for PV 29 is better characterized as a whole chemical risk determination rather than condition-of-use-specific risk determinations.

As explained later in this document, the revisions to the unreasonable risk determination (section 5 of the risk evaluation) would be based on the existing risk characterization section of the risk evaluation (section 4 of the risk evaluation) and would not involve additional technical or scientific analysis. The discussion of the issues presented in this *Federal Register* document and in the accompanying draft revision to the risk determination would supersede any conflicting statements in the prior PV 29 risk evaluation and the response to comments document (Ref.). With respect to the PV 29 risk evaluation, EPA intends to change the risk determination to a whole chemical approach without considering the use of PPE and does not intend to amend, nor does a whole chemical approach require amending, the underlying scientific analysis of the risk evaluation in the risk characterization section of the risk evaluation. EPA views the peer

reviewed hazard and exposure assessments and associated risk characterization as robust and upholding the standards of best available science and weight of the scientific evidence per TSCA sections 26(h) and (i).

EPA is announcing the availability of and seeking public comment on the draft superseding unreasonable risk determination for PV 29, including a list of the condition-of-use-specific risks driving the unreasonable risk determination for the chemical substance as a whole. For purposes of TSCA section 6(i), EPA is making a risk determination on PV 29 as a whole chemical. Under the revised approach, EPA is proposing to supersede the no unreasonable risk determinations (and withdraw the associated order) for PV 29 that were premised on a condition-of-use-specific approach to determining unreasonable risk.

C. What revision does EPA propose about the use of PPE for the PV 29 risk evaluation?

In the risk evaluations for the first ten chemical substances, as part of the unreasonable risk determination, EPA assumed for several conditions of use that all workers were provided and always used PPE in a manner that achieves the stated assigned protection factor (APF) for respiratory protection, or protection factor (PF) for dermal protection. In support of this assumption, EPA used reasonably available information such as public comments indicating that some employers, particularly in the industrial setting, provide PPE to their employees and follow established worker protection standards (e.g., Occupational Safety and Health Administration (OSHA) requirements for protection of workers).

For the January 2021 PV 29 risk evaluation, EPA assumed based on information provided by the manufacturer of PV 29 that workers use PPE—specifically, respirators with an APF ranging from 10 to 25—for eight conditions of use. However, in the January 2021 PV 29 risk evaluation, EPA determined that there is unreasonable risk to these workers even with this assumed PPE use.

When characterizing the risk to human health from occupational exposures during risk evaluation under TSCA, EPA believes it is appropriate to evaluate the levels of risk present in

baseline scenarios where no mitigation measures are assumed to be in place. It should be noted that, in some cases, baseline conditions may reflect certain mitigation measures, such as engineering controls, in instances where exposure estimates are based on monitoring data at facilities that have engineering controls in place. This approach considers the risk to potentially exposed or susceptible subpopulations of workers who may not be covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by a State Plan.

In addition, EPA believes it is appropriate to evaluate the levels of risk present in scenarios considering applicable OSHA requirements (e.g., chemical-specific permissible exposure limits (PELs) and/or chemical-specific PELs with additional substance-specific standards) as well as scenarios considering industry or sector best practices for industrial hygiene that are clearly articulated to the Agency. It should be noted that, in some cases, baseline conditions may reflect certain mitigation measures, such as engineering controls, in instances where exposure estimates are based on monitoring data at facilities that have engineering controls in place. Consistent with this approach, the January 2021 PV 29 risk evaluation characterized risk to workers both with and without the use of PPE.

When undertaking unreasonable risk determinations as part of TSCA risk evaluations, however, EPA does not believe it is appropriate to assume as a general matter that an applicable OSHA requirement or industry practice is sufficient to address the risk, applicable to all potentially exposed workers, or consistently and always properly applied. Mitigation scenarios included in the EPA risk evaluation (e.g., scenarios considering use of various PPE) likely represent what is happening already in some facilities. However, the Agency cannot assume that all facilities have adopted these practices for the purposes of making the TSCA risk determination. Additionally, as previously noted, self-employed individuals and public sector workers who are not covered by a State Plan are not covered by OSHA requirements. By characterizing risks using scenarios that reflect different levels of mitigation, EPA risk evaluations can help inform potential risk management actions by providing information that

could be used during risk management to tailor risk mitigation appropriately to address any unreasonable risk identified.

Therefore, going forward, EPA intends to make its determination of unreasonable risk from a baseline scenario that does not assume compliance with OSHA standards, including any applicable exposure limits or requirements for use of respiratory protection or other PPE. Making unreasonable risk determinations based on the baseline scenario should not be viewed as an indication that EPA believes there are no occupational safety protections in place at any location, or that there is widespread non-compliance with applicable OSHA standards. Rather, it reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by a State Plan, or because their employer is out of compliance with OSHA standards, or because EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements.

In accordance with this approach, EPA proposes that the draft revision to the PV 29 risk determination not rely on assumptions regarding the occupational use of PPE in making the unreasonable risk determination under TSCA section 6; rather, the use of PPE would be considered during risk management. This would represent a change from the approach taken in the 2021 risk evaluation for PV 29 and EPA invites comments on this draft change to the PV29 risk determination. As a general matter, when undertaking risk management actions, EPA intends to strive for consistency with applicable OSHA requirements and industry best practices, including appropriate application of the hierarchy of controls, when those measures would address an unreasonable risk; ensure the EPA requirements apply to all potentially exposed workers; and develop occupational risk mitigation measures to address any unreasonable risks identified by EPA. Consistent with TSCA section 9(d), EPA will consult and coordinate TSCA activities with OSHA and other relevant Federal agencies for the purpose of achieving the maximum applicability of TSCA while avoiding the imposition of duplicative requirements.

Informed by the mitigation scenarios and information gathered during the risk evaluation and risk management process, the Agency might propose rules that require risk management practices that may be already common practice in many or most facilities. Adopting clear, comprehensive regulatory standards will foster compliance across all facilities (ensuring a level playing field) and assure protections for all affected workers, especially in cases where current OSHA standards may not apply or be sufficient to address the unreasonable risk.

By removing the assumptions of PPE use in making the whole chemical risk determination for PV 29 would not alter the conditions of use that drive EPA's unreasonable risk determination for PV 29 as a whole chemical. The draft revision to the risk determination would clarify that EPA does not rely on the assumed use of PPE when making the risk determination for the whole substance. EPA is requesting comment on this potential change.

D. What is PV 29?

PV 29 is a high color strength, weather fast and heat stable pigment used in various industrial, commercial, and consumer applications. Domestic manufacture of PV 29 is conducted by a sole manufacturer. Imported PV 29 pigment, without being processed into a different product, makes up a very small market share of the PV 29 supply chain. Leading applications for C.I. Pigment Violet 29 include use as an intermediate to create or adjust color of other perylene pigments, incorporation into paints and coatings used primarily in the automobile industry, incorporation into plastic and rubber products used primarily in automobiles and industrial carpeting, use in merchant ink for commercial printing, and use in consumer watercolors and artistic color.

E. What conclusions did EPA reach about the risks of PV 29 in the TSCA risk evaluation based on the whole chemical approach and not assuming the use of PPE?

EPA determined that PV 29 presents an unreasonable risk to health driven by risk associated with the following conditions of use: manufacture (including import); processing (incorporation into formulation, mixture, or reaction products including paints and coatings and

plastic and rubber products; processing as an intermediate in the creation of adjustment of color or other perylene pigments; and recycling); industrial/commercial use of PV 29 in automotive (Original Equipment Manufacture (OEM) and refinishing) paints and coatings, coatings and basecoats, and merchant ink for commercial printing; and disposal of PV 29. By removing the assumption of PPE use in making the whole chemical risk determination for PV 29, there are no additional conditions of use or worker subpopulations that would drive the draft unreasonable risk determination. The same ten COUs would continue to drive EPA's unreasonable risk determination.

III. Revision of the January 2021 Risk Evaluation

A. Why is EPA proposing to revise the risk determination for the PV 29 risk evaluation?

EPA is proposing to revise the risk determination for the PV 29 risk evaluation pursuant to TSCA section 6(b) and consistent with Executive Order 13990, ("Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis") and other Administration priorities (Refs. 1, 3, and 4). EPA plans to consider revising specific aspects of the first ten TSCA existing chemical risk evaluations in order to ensure that the risk evaluations better align with TSCA's objective of protecting health and the environment. For the PV 29 risk evaluation, this includes the draft revision: 1) making the risk determination in this instance based on the whole chemical substance instead of by individual conditions of use (which would result in the new determination superseding the determinations and the withdrawal of the associated order of no unreasonable risk for the conditions of use identified in the no unreasonable risk order), and 2) clarifying that the risk determination does not rely on assumed use of PPE.

B. What are the draft revisions?

EPA is releasing a draft revision of the risk determination for the PV 29 risk evaluation pursuant to TSCA section 6(b). Under the revised determination, EPA proposes to conclude that PV 29, as evaluated in the risk evaluation as a whole, presents an unreasonable risk of injury to health when evaluated under its conditions of use. This revision would replace the previous

unreasonable risk determinations made for PV 29 by individual conditions of use, supersede the determinations (and withdraw the associated order) of no unreasonable risk for the conditions of use identified in the no unreasonable risk order, and clarify the lack of reliance on assumed use of PPE as part of the risk determination.

These draft revisions do not alter any of the underlying technical or scientific information that informs the risk characterization, and as such the hazard, exposure, and risk characterization sections are not changed except to the extent that statements about PPE assumptions in section 2.3.1.4 (Consideration of Engineering Controls and PPE), paragraph four, of the PV 29 risk evaluation would be superseded. The discussion of the issues in this Notice and in the accompanying draft revision to the risk determination would supersede any conflicting statements in the prior executive summary and section 2.3.1.4 from the PV 29 risk evaluation and the response to comments document (Ref. 8). Additional policy changes to other chemical risk evaluations, including any consideration of potentially exposed and susceptible subpopulations and/or inclusion of additional exposure pathways, are not necessarily reflected in these draft revisions to the risk determination.

C. Will the draft revised risk determination be peer reviewed?

The risk determination (section 5 in the January 2021 risk evaluation) was not part of the scope of the peer reviews of the first ten chemicals by the Science Advisory Committee on Chemicals (SACC). Thus, consistent with that approach, EPA does not intend to conduct peer review for the draft revised unreasonable risk determination for the PV 29 risk evaluation because no technical or scientific changes will be made to the hazard or exposure assessments or the risk characterization.

D. What are the next steps for finalizing revisions to the risk determination?

EPA will review and consider public comment received on the draft revised risk determination for the PV 29 risk evaluation and, after considering those public comments, issue the revised final PV 29 risk determination. If finalized as drafted, EPA would also issue a new

order to withdraw the TSCA section 6(i)(1) no unreasonable risk order issued in section 5.4.1 of the 2021 PV29 risk evaluation. This final revised risk determination would supersede the January 2021 risk determinations of no unreasonable risk. Consistent with the statutory requirements of TSCA section 6(a), the Agency would then propose risk management actions to address the unreasonable risk determined in the PV 29 risk evaluation.

IV. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA Risk Evaluation for C.I. Pigment Violet 29. EPA Document #740-R-18-015. January 2021. https://www.epa.gov/sites/default/files/2021-01/documents/1_final_risk_evaluation_for_c.i._pigment_violet_29.pdf.
2. Executive Order 13990. Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis. *Federal Register*. 86 FR 7037, January 25, 2021.
3. Executive Order 13985. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. *Federal Register*. 86 FR 7009, January 25, 2021.
4. Executive Order 14008. Tackling the Climate Crisis at Home and Abroad. *Federal*

Register. 86 FR 7619, February 1, 2021.

5. Presidential Memorandum. Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking. *Federal Register*. 86 FR 8845, February 10, 2021.

6. EPA. Proposed Rule; Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act. *Federal Register*. 82 FR 7562, January 18, 2017 (FRL-9957-75).

7. EPA. Final Rule; Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act. *Federal Register*. 82 FR 33726, July 20, 2017 (FRL-9964-38).

8. EPA. Summary of External Peer Review and Public Comments and Disposition for C.I. Pigment Violet 29 (PV29) (Anthra[2,1,9-def:6,5,10-d'e'f]diisoquinoline-1,3,8,10(2H,9H)-tetrone). January 2021. <https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0604-0126>.

Authority: 15 U.S.C. 2601 *et seq.*

Michael S. Regan,

Administrator.

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